The development of new diagnostic tools in food allergy

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Ethical review	Not approved
Status	Will not start
Health condition type	Allergic conditions
Study type	Observational invasive

Summary

ID

NL-OMON34148

Source
ToetsingOnline

Brief title
The analysis of diagnostic tools in food allergy

Condition

- Allergic conditions

Synonym
food allergy, food hypersensitivity

Research involving
Human

Sponsors and support

Primary sponsor: Universitair Medisch Centrum Utrecht
Source(s) of monetary or material Support: Ministerie van OC&W,Phadia, Nieuwegein,Phadia;Nieuwegein

Intervention

Keyword: allergen, diagnostics, food allergy, metabolomics

Outcome measures

Primary outcome

To develop a model to predict (the severity of) a food allergy.

Secondary outcome

-New biomarker(s) that can predict (the severity of) a food allergy

-To compare sensitivity, specificity and positive and negative predictive value

for different diagnostic tests: allergen chip, CAP, skin prick tests, basophil

activation test (BAT) and T cell activity

-Eliciting doses in walnut allergic patients

Study description

Background summary

The diagnosis of food allergy is difficult since the specificity and positive predictive value of routine tests (specific IgE in the blood, skin test) is low. This results in many false-positive results. The gold standard, the double-blind food challenge, is a time consuming and expensive diagnosis and also a burden for the patient. Therefore, the Minister of Health was advised by the Health Council in 2007 that research had to be conducted that can lead to the development of better tests for the diagnosis of food allergy.
Until now, the diagnosis is made using extracts of whole food. At this moment, many specific allergenic proteins are isolated and available for diagnosis. In some recent studies on apple and hazelnut allergy, it was showed that the severity of an allergic reaction can be better predicted when based on these components than using current diagnostic techniques. With a new developed allergen chip (ImmunoCAP ISAC) 103 allergenic components can be tested with a small amount of serum from the patient. By using this allergen chip we are able to determine for the major allergenic foods whether this new form of diagnosis is an improvement compared to current diagnostic techniques. We will do this by identifying the major allergen components in a retrospective study using a patient population already well characterized. Then we will perform a

prospective study and analyse these data on allergen components combined with anamnestic factors to develop a model to further optimize the diagnosis.
In recent research in collaboration with TNO Quality of Life we found indications that it is possible by using metabolomics (the measurement of metabolites) to find new biomarkers that can predict whether there is a food allergy or not and its severity. Therefore we want to investigate whether we can identify biomarkers and further improve the aforementioned model.

Study objective

The study consists of three parts:
a) Determine which specific components of a food allergen are important for (the severity of) the reaction.
b) Developing a model to predict the severity of a food allergy using specific components (obtained from part a) combined with the other components (inhalant and other food allergens) and data from patients' history.
c) Identifying new biomarkers to further improve the aforementioned model and the use of experimental allergy tests.

Study design

Part a: case-control, retrospective. Due to the exploratory nature of this section, we will Include as many patients as possible to determine which allergenic components are important in predicting an allergy. We will include a minimum of 30 patients per allergen (legumes, nuts, cow's milk, egg, shrimp, fish and latex (because of the associated food alelrgy). Depending on whether there is serum available from these patients from a previous study investigating the diagnosis of food allergy or a clinic visit, there will be a venepuncture to test the allergen components.
-Part b: cohort study ,prospectively. Patients that visit the outpatient clinic of Dermatology / Allergology complete a standardized questionnaire and a venepuncture will take place to test the allergenic components. A skin prick test will be performed when it has not already been done at the outpatient clinic. Also in this part, we want to include for each food as many patients as possible to test as many combinations of components combined with anamnestic factors as possible.
-Part c: cohort study. In patients that will undergo a food challenge, blood, urine and saliva will be tested for the investigation of a new biomarker.

Study burden and risks

The burden for most patients will consist of an oupatient clinic visit of about 30 minutes were a venepuncture will be performed and a questionnaire will be reviewed that has already routinely been completed by the patient. The risks of the venepuncture are negligible. The skin prick test, a routine test that usually has already been performed, causes itchy bumps that gradually disappear

after half an hour. There is a low risk of a mild or severe allergic reaction (very rare).
Patients who undergo a food challenge will be two full, non-consecutive days at the dermatology department in the UMCU. The food challenge is the best test to determine a food allergy. With this test, which is performed according to internationally established guidelines, increasing doses of food is administered to the patient until it is clear whether there is an allergy and to what extent. The challenge is stopped when a clear objective symptom will take place or a severe, persistent subjective complaint that lasts for longer than 45 minutes. We have extensive experience with this test and it is routinely used in the diagnosis of food alelrgy. Our experience learns us that the reactions that occur are usually mild, an anaphylactic reaction is rarely observed. Before the start of the challenge, patients get an infusion needle for quick medical action when needed to treat the allergic reaction. After the food challenge, patients are observed for at least 2 hours.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age

Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

Adults (from 18 years) with a (suspicion of) legume (peanut, soy), nut (hazel nut, pecan nut, cashew nut, walnut), cow's milk, fish, egg, shrimp or latex allergy

Exclusion criteria

congenital/acquired immunodeficiency
lymphoproliferative disease
systemic immunosuppression
Only when patients will undergo a food challenge:
instabile asthma
contra-indication for treatment with epinephrine (instabile angina pectoris, poor controlled hypertension or arrhythmia)
use of β-blocker or ACE inhibitor
pregnancy

Study design

Design

Study type: Observational invasive

Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Diagnostic

Recruitment

NL

Recruitment status:	Will not start
Enrollment:	0
Type:	Anticipated

Ethics review

Not approved

Date:	07-12-2010
Application type:	First submission
Review commission:	METC Universitair Medisch Centrum Utrecht (Utrecht)

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register	ID
CCMO	NL33531.041.10